Ventilator - induced lung and systemic inflammation in children with healthy lungs: an explorative study

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The primary objective is to study the level and time course of pulmonary pro- and anti-inflammatory mediators in children who need 2 hours of mechanical ventilation because they are undergoing an elective procedure.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON43254

Source
ToetsingOnline

Brief title
Ventilation and inflammation

Condition

- Respiratory disorders NEC

Synonym
Ventilator - induced lung injury

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Mechanical ventilation, VILI

Outcome measures

Primary outcome

The primary endpoint is the level and time course of pulmonary inflammatory

mediators including G-CSF, GM-CSF, IFN-, IFN-, IL-1, IL-1RA, IL-2, IL-2R, IL-4,

IL-5, IL-6, IL7, IL-8, IL-10, IL-12, IL-13, IL-15, IL-17, TNF-alpha

Secondary outcome

Level and time course of systemic inflammatory mediators (i.e. G-CSF, GM-CSF,

IFN-, IFN-, IL-1, IL-1RA, IL-2, IL-2R, IL-4, IL-5, IL-6, IL7, IL-8, IL-10,

IL-12, IL-13, IL-15, IL-17, TNF-alpha)

Level and time course of pulmonary 1-antitrypsin concentrations

Level and time course of pulmonary sRAGE concentrations

Level and time course of systemic sRAGE concentrations

Study description

Background summary

Nowadays mechanical ventilation is standard for a pediatric intensive care unit (PICU), where 64% of the patient*s need mechanical ventilation for at least 24 hours With the development of the ventilation, there also came a critical insight that ventilation can have the opposite effect. Instead of giving the lungs time to heal, it can induce ventilator-induced lung injury. The consequence for mechanical ventilation on healthy lungs remains unclear. Several studies are suggesting that mechanical ventilation also causes VILI in children who do not have lung pathology. The long-term effects of ventilation children on developing healthy lungs are also not known.

Study objective

The primary objective is to study the level and time course of pulmonary pro- and anti-inflammatory mediators in children who need 2 hours of mechanical ventilation because they are undergoing an elective procedure.

Study design

Prospective observational with invasive measurements

Study burden and risks

The risks associated with this study are minimal based on the following arguments: a) during the catheterisation, patients are fully anesthetised (including paralyzed) and under constant tight observation, so any change in vital parameters is noted immediately, b) blood samples are only taken from an indwelling arterial catheter that is inserted for the catheterisation and c) endotracheal suctioning is routinely performed in mechanically ventilated patients; for this study the suctioning specimens are collected to measure the pulmonary inflammatory response so no extra suctioning procedures will be performed

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

• Written Informed consent obtained

Exclusion criteria

• Patients with a history of allergic or respiratory diseases
• Known chromosomal disorder
• Known immunological disorders
• Recent episode of mechanical ventilation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	35
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-12-2016

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	Aangevraagd
CCMO	NL59436.042.16